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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,426	09/23/2003	Bahar Reghabi	047711-0321	4240
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FOLEY & LARDNER 2029 CENTURY PARK EAST SUITE 3500 LOS ANGELES, CA 90067			EXAMINER SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Tata

Office Action Summary

Application No.

10/669,426

Applicant(s)

REGHABI ET AL.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 7, in paragraph [0030], the last sentence uses the word “an” in front of the word “quantifiable” wherein grammatically the correct word is “a”. In paragraph [0031], the reference to Fig. 5 as an example in light of Fig. 1 is not clear. The flow chart of Fig. 5 does show a specific number of sensors like the view of Fig. 1 specifically shows elements 12a-12e as sensors.

On page 9 in paragraph [0040], it appears that the word “be” (line 6) should be added to the sentence between the words “may” and “positioned.”

On page 11 in paragraph [0044], it appears that the word “be” (line 4) should be added to the sentence after the word “may.”

On page 12 in paragraph [0049], it appears that the word “be” (line 4) should be added to the sentence after the word “may.”

On page 13 in paragraph [0052], it appears that the word “be” (line 7) should be added to the sentence between the words “may” and “positioned.”

On page 14 in paragraph [0057], it appears that the word “be” (line 4) should be added to the sentence after the word “may.” In paragraph [0059] on line 3, it appears that the word “to” after the word “attendant” is superfluous. If it is not a superfluous word, the sentence is unclear.

On page 15 in paragraph [0062], it appears that the word “be” (line 4) should be added to the sentence after the word “may.”

On page 17 in paragraph [0067], it appears that the word “An” (line 8) should be the word “A.” In paragraph [0071], it appears that the word “may” (line 3) should be added to the sentence after the word “invention.”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23 and 26–41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation “the at least one implantable sensing element” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 recites the limitation “the single site” in lines 7–8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 4, 8, 9, 11, 12, 26, 30, 31, 33, are rejected under 35 U.S.C. 102(b) as being anticipated by Gord et al., U.S. Patent 5,999,848.

Gord discloses implanting an implantable sensor at a single site in a patient (Figs. 1–4; column 7, lines 28–32; column 8, lines 35–36), an implantable sensor having a housing within which are disposed a plurality of implantable sensing elements (Figs. 3A–5C); and reading an output from at least one of the implantable sensing elements (column 7, lines 34–41), evaluating

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a patient based on an output read from at least one implantable sensing element (column 7, lines 36–53); wherein a plurality of parameters are read from an implantable sensor at a single site (column 7, lines 31–34; column 13, lines 23–25), and wherein an output read from at least one of the implantable sensing elements is a quantifiable value (column 7, lines 33–34 and 45–48); wherein at least one of an implantable sensing elements is a biological parameter sensor, a physiological parameter sensor, an analyte sensor (column 7, lines 30–34); wherein reading/evaluating a patient based on an output from at least one of an implantable sensing elements comprises reading an output from an implantable sensing element that responds to glucose (column 7, lines 30–33 and 45–48), temperature (column 7, lines 30–34), pH (column 7, lines 30–33); administering therapy to a patient based on an output read from at least one implantable sensing element (column 7, lines 44–45 and 51–53 wherein regulation of the insulin infusion is the therapy being administered).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5–7, 10, 13–25, 28–29, 32, and 34–43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gord et al., U.S. Patent 5,999,848.

Gord discloses the claimed invention but does not disclose expressly reading/evaluating a patient based on an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate, blood oxygen saturation, blood pressure, and potassium; and administering therapy/evaluating the patient comprises administering therapy/evaluating the patient for myocardial infarction, myocardial ischemia, angina, adjusting a function and placement of an implantable cardiovascular defibrillator disposed within the patient, sepsis, septic shock, a patient receiving extracorporeal membrane oxygenation, a patient undergoing cardiac bypass, a patient during dialysis; and classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element; and a patient is in a surgical and an intensive care environment; and implanting an implantable sensor at a single site in a triage patient and in a patient in the field. It would have been an obvious matter of engineering design choice to a person of ordinary skill in the art to modify the implantable sensing elements to sense/evaluate the biological and physiological parameters and administer/evaluate therapy to a patient as taught by Gord, to include those parameters and therapies listed in the claimed limitations in paragraph 7 above, because Applicant does not disclose that these limitations provide an advantage or solves a stated problem over and above the like/similar claimed limitations listed in paragraph 4 above. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform

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equally well with the claimed limitations as taught by Gord, because each of these sensors are configured to sense a different parameter and any configuration of an implantable, daisy-chainable device allows one or more, e.g., multiple, sensors to be employed within the device, with the data sensed by each sensor being convertible to an appropriate form and transferable through conductors to perform a desired medical function as needed for the benefit of the patient.

Therefore, it would have been an obvious matter of design choice to modify the invention of Gord to obtain the invention as specified in the claims listed in paragraph 7 above.

In the alternative, for the above mentioned sensing elements, therapy, and the environment and location of a patient it is well known in the art for sensing elements to respond to lactate, blood oxygen saturation, blood pressure, etc., and to administer therapy for myocardial infarction, myocardial ischemia, angina, etc., and for patients to be in surgery, triage, etc. for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Gord to include the claimed limitations above for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



TLS

January 3, 2006

3 January 2006

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GEORGE R. EVANISKO
PRIMARY EXAMINER

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